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Application No. 09/943,420

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- II. Claims 40-41, 44-59, 61-70, and 72-74, drawn to compounds of formula (I), formula (XXIX) or formula (XXX) where Y is a heterocyclyl other than those of Group I above, corresponding composition and method of use
- III. Claims 41, 50-52, 58-64 and 72-74, drawn to compounds of formula (XXIX) or formula (XXX) where Y is NR^nR^p , corresponding composition and method of use

In response to the restriction requirement, Applicants elect Group I with traverse.

Applicants respectfully submit the restriction requirement is improper for the following reasons.

The present restriction requirement appears to be an attempt by the Examiner to define inventions within individual claims. Applicants submit that it is clearly established that the USPTO cannot require an applicant, under the guise of §121, to divide up the embodiments of a single Markush claim. Specifically, the Court of Customs and Patent Appeals has clearly stated:

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *In re Weber*, 198 USPQ 328, 331 (CCPA 1978) (emphasis in original).

The Examiner's attention is further directed to MPEP §803.02 where restriction practice with respect to Markush claims is discussed in connection with the decision in *In re Weber*. In particular, MPEP §803.02 states:

Since the decisions in *In re Weber*... it is improper for the office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common

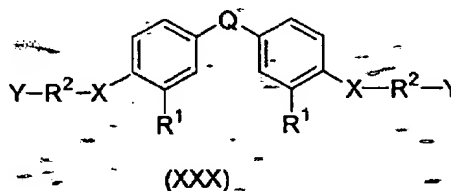
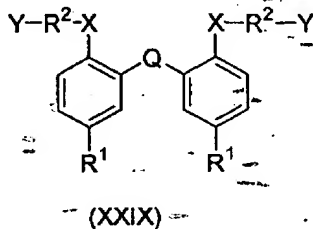
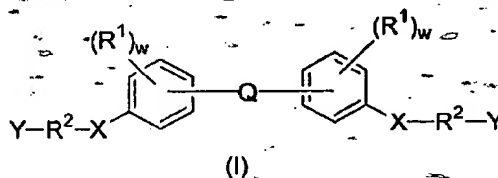
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utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

In the present case, the Examiner has alleged without substantiation that "Groups I-III are drawn to structurally dissimilar compounds. They are made independently and used independently." (Office Action, page 2) Applicants respectfully submit that all of these statements are inaccurate. First, all of the compounds of the present invention are sodium channel modulators and thus share a common utility. It is inappropriate, therefore, to assert the compounds are "used independently."

Second, Groups I and II, as defined by the Examiner, *both* include compounds of the structures of formulas (I), (XXIX), and (XXX):



The only difference between Groups I and II is whether a single, terminal substituent Y, in these formulas, is a heterocycle having one nitrogen atom as the only ring heteroatom or whether it is a heterocycle of a different description. Similarly, Group III includes compounds of formulas (XXIX) and (XXX). Again, the distinguishing characteristic of Group III is the definition of the substituent Y. The fact that Groups I, II, and III include the same basic structural formulas supports Applicants' position that the compounds share a substantial structural feature. Merely indicating that choices of one substituent on the structural core are in different search classifications is not sufficient to establish that the compounds are "structurally dissimilar."

Furthermore, contrary to the Examiner's statement that the compounds are "made independently," compounds in all three of the presently defined groups can be made by a similar

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process. See, for one particular example, the discussion of the synthesis of compounds 27 to 39 on page 69, line 1 through page 71, line 7 of the present specification. Compounds 27 to 39 include compounds 32-35 and 39 in which Y is a heterocycle containing one nitrogen ring atom (corresponding to Group I), compound 38 in which Y is a morpholino group (corresponding to Group II), and compounds 27-31, 36, and 37, in which Y is a group of the form $\text{NR}^{\text{R}'}\text{R}^{\text{R}''}$ (corresponding to Group III), all of which follow the same synthetic scheme except for the substitution of a single reagent. Applicants submit therefore, the Examiner's characterization of the compounds as "structurally dissimilar", "made independently", and "used independently" is inappropriate.

Accordingly, the Examiner has failed to demonstrate a lack of unity in the claims as originally presented. Thus, the requirement that requires restriction *within* individual claims is improper and should be withdrawn.

In addition, were the claims to be modified to conform to the present restriction requirement, it would mean redefining the invention in a manner conceived of not by the inventors but by the Examiner. This course would lead to the dilemma foreseen in *In re Weber* where the invention as defined by the Examiner is not necessarily described in the specification. Clearly forming sub-genuses of compounds based on USPTO search classification schemes of certain substituents, does not necessarily correspond to the subgenuses determined by the inventors from their research. A restriction practice in which the genus of compounds that is allowed to be claimed is defined *ex-post facto* by the Examiner leaves the Applicant incapable of drafting a specification with proper-antecedent basis for the claims that ultimately result from the examination process.

Applicants are further required under 35 U.S.C. §121 to elect a single disclosed species. Applicants traverse the election of species requirement. However, to comply with the requirement, Applicants elect compound 1, which is depicted in Table I on page 5 of the specification and the synthesis of which is described in Example 1 page 62, lines 8 to 28. Claims 40, 42, 43, 46-53, 55-58, 63, 64, 67, and 69-74 read on the elected compound.

In making the election of species requirement, the Examiner states "Claims are generic to a plurality of disclosed patentably distinct species comprising the species disclosed in the

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examples." (Office Action, page 3) In this statement, the Examiner appears to be defining *each* disclosed compound as a separate species. It is unreasonable for the Examiner to suggest that no more than a single compound can be examined without creating a serious burden on the Examiner. Given the structural similarity among the compounds depicted in Table I, pages 5-34, the synthesis of which is described in the examples, one can easily envision how a search could be directed to multiple compounds at the same time. Accordingly, the present election of species requirement is improper and should be withdrawn.

Should there be any issues that can be resolved by telephone, the Examiner is invited to telephone the undersigned Agent for Applicants at (650) 808-3764.

Respectfully submitted,

Date: February 28, 2003

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